

Quality you trust,
convenience
you need

BioSupplies
Biological material solutions

Cell Therapy

Human Serum
Albumin



Grifols offers a pharmaceutical-grade human serum albumin for starting material, ancillary and excipient use that is fully compliant with regulations of the European and the United States pharmacopeias (EP and USP).

The product presented here is not for therapeutic use.

GRIFOLS

From Pharma to Pharma. From Science to Solutions

At Grifols Bio Supplies, we believe cell therapy is the future of medicine. Backed by 115+ years in plasma science, we provide high-quality, ethically sourced biological materials to help pharma and biotech companies develop life-changing therapies.

Our mission is to ensure every patient, anywhere, can access the best therapies to improve their health and quality of life. This is why we supply trusted human-derived materials that accelerate cell therapy research and development.

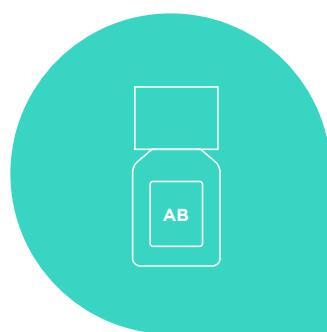
As a leading pharmaceutical company specialized in human biological materials, we stand for excellence, safety, innovation, collaboration, and community—values that guide our work and ensure reliability and safety for our clients.

To accelerate cell therapy, we rely on 2 main product lines:



CELL SOURCING

Providing a reliable and scalable cell supply, ensuring consistency, minimizing variability^{1,2} and reducing production delays.



CELL CULTURE SUPPLEMENTS

Optimizing cell culture performance³ and ensuring well-regulated, stable, and efficient conditions for cell expansion.



Grifols extends its expertise in hemoderivates to use therapeutic-grade products as excipient and ancillary materials

Grifols is a leading global healthcare company that develops plasma-derived medicines and other innovative biopharmaceutical solutions that enable millions of patients around the world to lead more productive lives. Grifols provides high standards of quality and safety throughout the entire plasma processing process, from collection to delivery of the final drug to patients.

Human serum albumin (HSA) is the most abundant protein in human blood plasma, constituting about half of the serum proteins. It is used as a treatment to restore circulatory

volume and protein loss in pathophysiological conditions, but also it can be used in manufacturing processes as excipient and ancillary material, stabilizing, protecting and transporting biological molecules.⁴

Within cell therapy, HSA is used either as an **ancillary material/raw material**; which is a substance used during the manufacturing process that comes into contact with the product but is not intended to be present in the final product or as an **excipient**; which is a substance other than the active pharmaceutical ingredient (API) that is included in the formulation.



ANCILLARY MATERIAL/RAW MATERIAL

Cell isolation and expansion, preventing aggregation and maintaining a stable and nutritious environment for cell development

1

2

Cryopreservation and post-thaw functionality, it coats the surface of the cells, ensuring safekeeping during the freezing and thawing processes

3



EXCIPIENT

Cell separation, protecting modified CAR-T cells during separation, improving efficiency

4

HSA as an excipient is used for **final formulation**, provides an excellent shield against toxins and reactive oxygen species reducing stress-induced damage and stabilizes the cell suspension, ensuring viability until administration.⁴

Human Serum Albumin

FOR VIABILITY AND CELL CULTURE QUALITY

HSA is manufactured under strict quality standards to ensure purity consistency and regulatory reliability, achieving a therapeutic-grade product. It is sourced from US and EU plasmapheresis centers that are compliant with the Food and Drug Administration (US FDA) and the European Medicines Agency (EMA) regulations, as well as European pharmacopeia and United States pharmacopoeia (EP/USP) standards. Its stability, binding capacity, and biocompatibility make it a valuable excipient in cell therapy and biopharmaceutical manufacturing, supporting cell viability, protein stabilization, and formulation integrity.

COMPOSITION INFORMATION

Tests	Specifications
Purity	>96% albumin
Potassium	<1 mEq/L
Citrate	<0.1 mmol/L
Sodium	150 mEq/L
pH	7.1



SAFETY, QUALITY, CONSISTENCY

HSA supplied in EP/USP formats to meet the stringent requirements of cell therapy development and manufacturing.

Rigorous safety protocols and full traceability from donor to final product.



REGULATORY COMPLIANCE

Grifols has valuable expertise in regulatory compliance in different parts of the world.

We can help to smooth the pathway to product registration in all corners of the world.



STRONG SUPPLIES CAPABILITIES

Plasma collection centers, manufacturing facilities and logistics hub across US and Europe.

Our infrastructure and regulatory expertise ensure reliable global delivery, even in high-demand situations.

Human Serum Albumin

AVAILABLE FORMATS



VIALS

Grifols Bio Supplies offers high-quality HSA in convenient vial formats, tailored for use in biotech, diagnostic, and pharmaceutical manufacturing. Each vial contains plasma-derived albumin that meets USP and EP standards, helping to maintain safety, consistency, and full traceability. HSA is widely used as an excipient in the pharmaceutical and biotechnology industries.

TRADITIONAL PACKAGING

- Reduce risk of leachable assuring product stability and safety
- Compatible with sterile fill-finish process in manufacturing.
- Secure containment minimizing exposure risks during handling

SAFETY

Sterility is preserved with a secure closure system: a rubber stopper and aluminum seal.

PRODUCT OPTIONS

20% HSA solution in 100ml bottles
25% HSA solution in 100ml bottles



BAGS

Grifols albumin in bags combines therapeutic-grade quality with innovative packaging to meet the needs of cell culture in cell therapy. Grifols albumin in bags builds on the success and reliability of Grifols therapeutic-grade albumin in vials.

INNOVATIVE PACKAGING

Designed for convenience and safety:

- Easy-to-open protective overwrap that prevent evaporation
- Easy to storage
- Wider base to reduce injury risk
- A twist-off cap for quick access

ENHANCED SAFETY

Designed with a tamper-evident seal to maintain sterility until use.

PRODUCT OPTIONS

25% HSA solution in 100-ml bags

Empowering Innovation from the Source

At Grifols Bio Supplies, we know that every great therapy begins with a reliable foundation. That's why we've built an infrastructure that delivers confidence at every stage of your process. From donor to delivery, every element of our supply chain is designed to give you what you need most: consistency, flexibility, and reliability—backed by global donor network, robust supply capabilities, and end-to-end superior quality and safety!

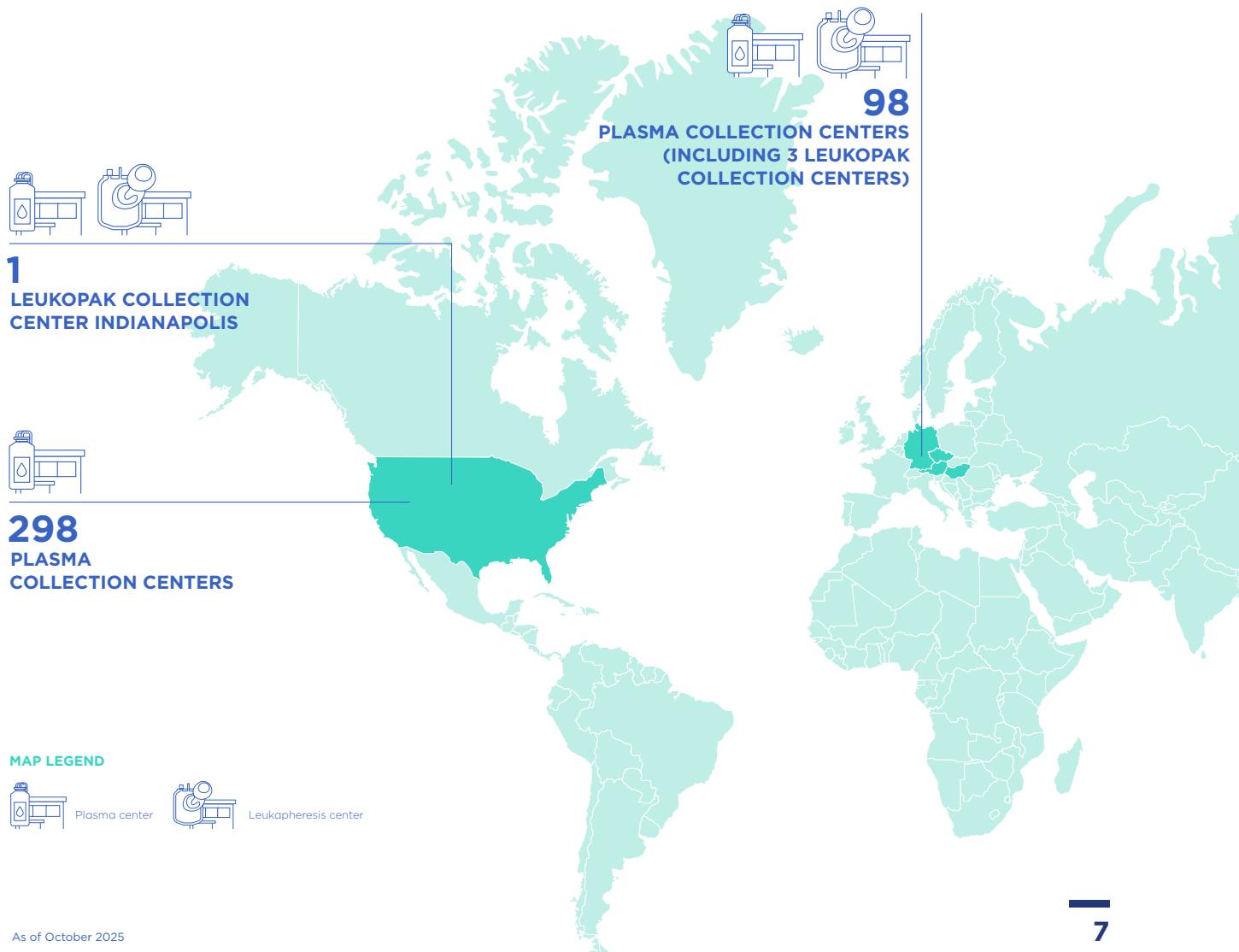


Empowering Innovation from the Source

STRONG SUPPLY CAPABILITY

In a field where timing is critical, Grifols Bio Supplies delivers consistency and quality through a strong global supply infrastructure.

- Robust, global supply infrastructure that meets demands of even the most time-sensitive workflows
- Manufacturing facilities in EU and USA
- Vertically integrated model: from plasma collection to final product.
- Reliable delivery following good distribution practice for standard and specialized applications.



Empowering Innovation from the Source

REGULATORY EXPERTISE

With decades of experience navigating global regulatory frameworks, Grifols provides comprehensive support for product registration, compliance, and documentation.

- Fully compliant with FDA and EMA standards
- Smooth market access
- Sustained product confidence

Documents provided:

- CoA
- BSE/TSE statement
- Annually updated plasma master file (PMF)
- Albumin technical dossier with stability and viral safety data
- Genetically modified organism (GMO) statement
- Residual solvent statement
- Nitrosamines and melamine statement
- Elemental impurities statement



Empowering Innovation from the Source



QUALITY, SAFETY AND CONSISTENCY

Built for excellence. Trusted for performance. Every step of the process—from plasma collection to final packaging—is governed by strict safety standards and regulatory compliance, ensuring reliable performance across diverse applications.

- State-of-the-art facilities and advanced technologies
- Manufacturing governed by strict **GMP protocols** and full compliance with **US FDA** and **EMA** standards
- Adherence to current good manufacturing practices and to the International Quality Plasma Program (**IQPP**) from the Plasma Protein Therapeutics Association (**PPTA**)
- Therapeutic-grade quality with licensed medical products (USP and EP) and full traceability across the supply chain
- Reliable delivery following good distribution practice for standard and specialized applications

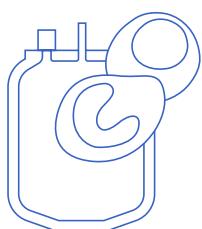
Meet our Cell Sourcing and Cell Culture solutions to support therapeutic success

To support therapeutic success for cell therapy manufacturing, we accompany the process from beginning to end. At Grifols Bio Supplies, not only high quality EP/USP-grade albumin and male AB serum is offered to support the growth and stability of the cells, but also leukopaks, the starting material in the manufacturing of advanced cell therapies^{5,6} essential for any cell therapy.

Explore our full range of bio supply solutions at biosuppliesproducts.com



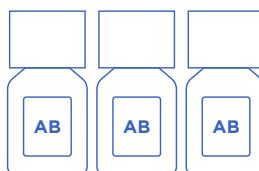
CELL SOURCING



LEUKOPAKS

Derived through leukapheresis, these blood-based products are rich in mononuclear leukocyte- primarily lymphocytes and monocytes- and are designed to meet the evolving needs of R&D and pharmaceutical manufacturing.

CELL CULTURE



MALE AB SERUM

A widely used supplement in cell culture media, male AB serum offers a balanced mix of growth factors, hormones, and attachment agents.⁷ Derived exclusively from male donors with AB blood type, it minimizes immunological risks and ensures high consistency across applications.

Your Ally in Cell Therapy

At Grifols Bio Supplies, we're committed to advancing cell therapy by providing high-quality, ethically sourced human biological materials.

We understand the challenges of developing life-changing treatments and aim to make that journey faster, safer, and more reliable.

Our global donor network and supply strength allow partners to focus on innovation, research, and improving patient outcomes.

**We stand for trust.
The certainty that when you choose the best, you are in the best hands.**



**Choose Grifols
and enhance your
cell culture processes
with a trusted partner**

biosupplies_contactus@grifols.com

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For ordering information,
contact us here:



biosupplies_contactus@grifols.com